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Novel insight into pressurization of the male and female urethra through application of a multi-channel fibre-optic pressure transducer: Proof of concept and validation

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Purpose: To confirm feasibility of recording pressure along the length of the urethra using a multi-sensor fibre-optic pressure catheter; to identify the spatial and temporal features of changes in pressure along the urethra at sites related to specific striated pelvic floor muscles; and to investigate the relationship between urethral pressures and activation of individual pelvic floor muscles estimated from ultrasound imaging.

Materials and Methods: Proof-of-concept study including one male (47 years old) and one female (33 years old). A multi-sensor fibre optic pressure catheter (10 mm sensor separation) was inserted into the urethra. Pressure data were recorded simultaneously with trans-perineal ultrasound imaging measures of pelvic floor muscle activity during sub-maximal and maximal voluntary contractions and evoked coughs.

Results: Pressure changes along the urethra were recorded in all tasks in both participants. Face validity of interpretation of pressure measures with respect to individual muscles was supported by correlation with ultrasound-measured displacements induced by the relevant muscles. Onset of pressure increase occurred in a distal to proximal sequence in the urethra of the male but not the female during voluntary contraction. Peak urethral pressures varied in location, timing and amplitude between tasks. Evoked cough induced in the greatest urethral pressure increase across all tasks for both participants.

Conclusions: The high spatial resolution pressure catheter provide viable and valid recordings of urethral pressure in a male and female. Data provide preliminary evidence of sex differences in spatial and temporal distribution of urethral pressure changes.

Keywords: Catheters; Pelvic floor; Pressure; Reproductive and urinary physiological phenomena

INTRODUCTION

Urinary continence requires coordination of smooth and striated muscles [1] to constrict the urethra, in addition to contributions from vascular and connective tissues [2]. Striated muscles include the levator ani, the striated urethral

sphincter (SUS), the bulbocavernosus (BC) and ischiocavernosus [3]. Similar muscles are available in males and females, although the levator ani (including puborectalis [PR]) are emphasized in females because of involvement in stress urinary incontinence, whereas SUS is emphasized in males because of its role in post-prostatectomy incontinence [4]. Each muscle's anatomy indicates pressure will be generated at different locations along the urethra, yet the amplitude and timing of their contribution to pressure is unclear because of limitations of current technology. Although recent investigations using transperineal ultrasound (US) imaging have provided insight into the coordination between muscles [5,6], these measures infer muscle activation from motion of pelvic landmarks and cannot provide information of pressure. Detailed evaluation requires technology with spatial resolution sufficient to record pressures from each muscular component, temporal resolution to detect rapid increases in pressure during dynamic tasks, and physical properties that limit distortion of the urethral wall.

Urodynamic testing typically uses catheter devices with two pressure transducers (one each in the bladder and urethra [7]) or a single pressure sensor that records pressure distribution along the urethra during withdrawal. A single sensor cannot be used to study coordination between different muscles, and its exact placement may differ between participants and/or tests. Pressure recordings during catheter withdrawal can only detect pressure during a static state. This cannot inform dynamic interaction between muscles, and when tested during contraction it assumes that muscle activation remains constant. This is problematic because pelvic floor muscles fatigue rapidly [8]. One study has reported differences in the timing of urethral pressure increase at multiple sites during cough and Valsalva in healthy females [9]. Further, measures of muscle activation with electromyography (EMG) and US in females [10] and males [11] report differences in timing between individual pelvic floor muscles and changes in muscle activation with incontinence [4,10]. This provides preliminary support for the notion that when specific muscles contract may be relevant for dysfunction. This requires measurement of urethral pressures with high spatial resolution.

Use of multi-sensor catheters in the oesophagus is common but these devices are generally too large and inflexible for the urethra. Recent studies of colon function have employed a multi-sensor fibre optic manometry catheter [12-14] to provide insight into peristaltic smooth muscle contractions [15-17]. To enable this analysis, a catheter with high temporal and spatial resolution was developed to record multiple pressure signals simultaneously using fibre optic technology that minimizes the required catheter diameter. A major advantage is that the technology does not involve fluid or air flow to or from the catheter, which limits temporal resolution and can introduce errors due to catheter compression outside the sensing region. Fibre optic technology has potential to provide the necessary detail required to understand how the multiple continence mechanisms interact to control urethral pressure.

This study aimed to: i) test the feasibility of recording urethral pressure using a multi-sensor fibre optic pressure catheter in one male and one female; ii) present initial findings of temporal and spatial features of urethral pressure during static and dynamic tasks; and iii) test the face-validity of the interpretation of pressure measures by comparing urethral pressure with displacements observed on US that infer muscle activation.

MATERIALS AND METHODS

1. Participants

Two participants (one male [47 years old]; one female [33 years old]) with no history of urological symptoms volunteered for this proof of concept and validation study. The institutional Medical Research Ethics Committee approved the study (approval number: 2010000545), which was conducted in accordance with the principles expressed in the Declaration of Helsinki. Participants provided written consent.

2. Instrumentation

A 32-sensor fibre optic pressure transducer catheter with between-sensor spacing (centre-to-centre) of 10.4 mm, diameter of 3.0 mm and total length of 420 mm [12,14] was used to measure urethral pressure (Fig. 1). This device was a customized variant of the device used to study colonic pressure patterns [15-17]. In brief, each pressure sensing element consisted of a metallic substrate 7.5 mm in length containing two optical fibres. The fibres each contained a fibre Bragg grating (FBG) designed to reflect a different wavelength of light, which enabled all gratings to be monitored simultaneously using an optical spectrometer (FBG-Scan 804D; FBGS International, Geel, Belgium). This method enables large numbers of FBGs to be placed along a single fibre without increasing the overall diameter. As pressure is increased near each sensor, the wavelengths reflected by the FBGs change proportional to the applied pressure, providing a method to monitor changes in pressure at each sensor location simultaneously. Data were recorded at 500 Hz via custom written LabVIEW software (National Instruments, Austin, TX, USA).

3. Participant preparation and procedure

Participants sat reclined on a plinth with a back-rest at 30° from vertical and knees extended. For both participants
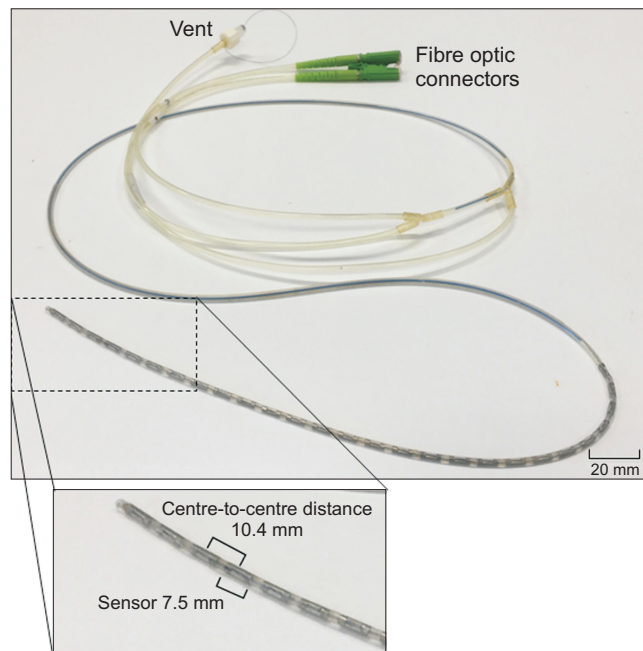

Fig. 1. Images of the multi-channel fibre optic pressure catheter showing the entire device (top) and a close-up view of a sensing region which demonstrates the length of the individual sensors (7.5 mm) and the centre-to-centre distance of the sensors placed in the device (10.4 mm) (inset).

the catheter was inserted using an aseptic technique following administration of lubricating anaesthetic (Lignocaine 2% gel; Pfizer, Sydney, NSW, Australia). The catheter was held at the external urethral meatus with a gloved hand. An US transducer (XC6-1; Supersonic Imagine, Aix-en-Provence, France) was placed on the abdominal wall to identify the location of the catheter in the bladder (Fig. 2A). The location was confirmed by an absence of pressure increase on the sensors in the bladder during voluntary pelvic floor muscle contractions. Then, the US transducer was placed in midsagittal line on the perineum for the experiment's duration (Fig. 2B). Imaging data were collected in video format (25 Hz) using a high-resolution US device (Aixplorer; Supersonic Imagine). US and pressure data were synchronized by trigger events at the beginning and end of each trial and recorded using a Power 1401 analogue-to-digital converter and Spike2 software (CED, Cambridge, UK). Participants performed four tasks to investigate spatial and temporal features of urethral pressure increase by individual striated muscles (Table 1).

4. Data analysis

Pressure data were imported into Matlab (r2017a; The Mathworks, Natick, MA, USA) and analyzed using custom written programs. Of the 32 channels available on the catheter device, only data recorded at the 14 pressure channels
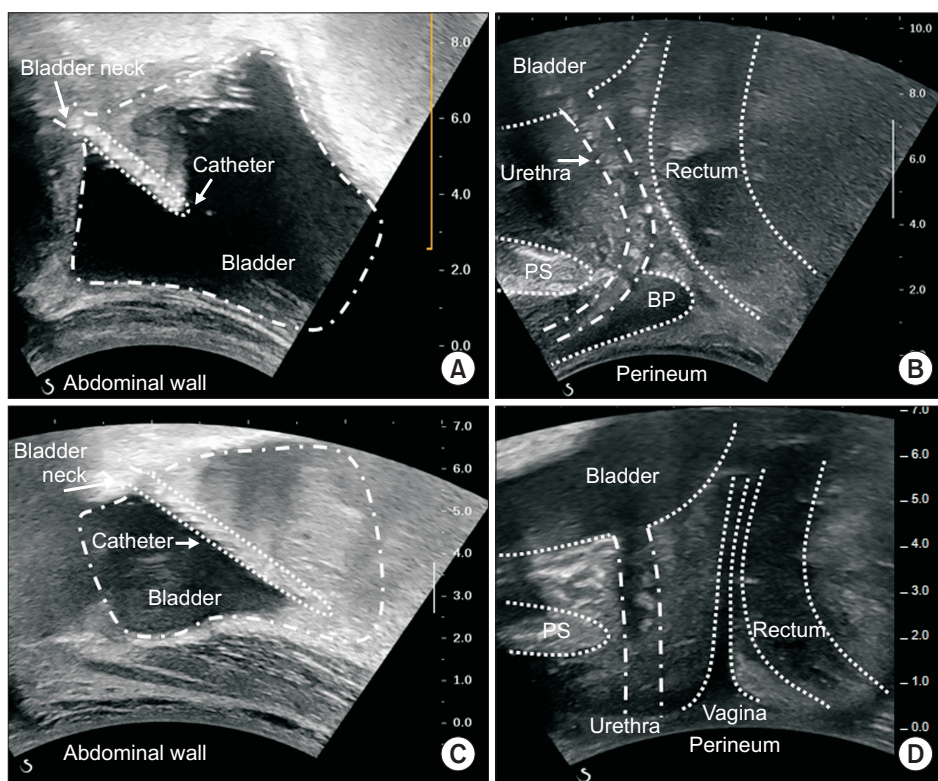

Fig. 2. Ultrasound (US) images of the pressure catheter *in situ*. Transabdominal US images show the length of catheter inside the bladder in the male (A) and female (C). Transperineal US images show the location of the pressure catheter (inside the urethra) relative to pelvic structures in the male (B) and the female (D). BP, bulb of the penis; PS, pubic symphysis.

Table 1. Tasks used to investigate the coordination of urethral pressurization by the striated muscles

Task	Description
Submaximal voluntary pelvic floor muscle contraction	Three repetitions were performed to an intensity of 3/10 on a modified Borg scale (maximal voluntary contraction=10)
Ramped pelvic floor muscle contraction	Two repetitions of ramped contraction were performed beginning at rest and increasing to maximum voluntary contraction over 5 seconds
Evoked cough	Two repetitions of evoked cough were recorded following inhalation of nebulized capsaicin dissolved in saline using a concentration that was sufficient to evoke at least two involuntary coughs
Sustained maximum voluntary contraction of pelvic floor muscles	A single contraction performed with maximal effort for 60 seconds with strong verbal encouragement

Table 2. Pelvic landmarks recorded with transperineal ultrasound imaging in the male and female including interpretation of motion

Landmark	Male	Female
Pubic symphysis	A reference landmark to account for ultrasound transducer movement [1,6]	A reference landmark to account for ultrasound transducer movement
Ano-rectal junction	Ventral motion represents puborectalis muscle contraction [1,6]	Ventral motion represents puborectalis muscle contraction [18]
Mid-urethra distal to prostate	Dorsal motion represents striated urethral sphincter contraction [1,6]	Not applicable
Bulb of penis	Ventral motion of posterior border represents bulbocavernosus contraction [1,6]	Not applicable
Tissue superficial to the pubic symphysis	Not applicable	Dorsal motion represents bulbocavernosus contraction [18]

nearest to the catheter tip were considered for analysis for the male participant, and data from the 12 channels nearest to the catheter tip were considered for the female participant. The number of channels used for analysis was determined by observation of the pressure record and estimation of the number of sensors in the bladder (from the length of catheter measured from trans-abdominal US [Fig. 2A] and the estimated urethral length visible on transperinal US (Fig. 2B). Locations were described with reference to the distance from the urethrovesical junction.

Amplitude and temporal features of urethral pressure increase were detected automatically for each channel across tasks. First, the time of onset of urethral pressure increase was identified as the time at which pressure exceeded an increase of 5 cmH_2O from rest. Second, the time and amplitude of peak urethral pressure were identified. Pressure amplitudes at individual sensor locations were averaged across repetitions for each task and the slope of the increase was calculated between the onset and peak locations (Onset slope). Data were considered in terms of identification of the region(s) of greatest pressure and comparison of timing and amplitude between locations and tasks. Temporal data were expressed relative to time of the earliest increase in pressure at any location.

To enable comparison between urethral pressure and mo-

tion on US, displacements observed on US were analyzed frame-by-frame using a pixel-tracking software package (Tracker, ver. 4.11.0). First, a region of interest (ROI) was manually selected for each landmark and the software automatically recorded the position that best matched the ROI in each subsequent image. The analysis was performed at four points of interest that have previously been validated to reflect activation of individual pelvic floor muscles [6]. Each landmark and muscles represented the landmark's motion is described in Table 2 [1,6,18]. Displacements of the landmarks, as an index of contraction of each muscle, were compared with urethral pressures recorded from the pressure sensors identified to sit adjacent to them.

The location of individual sensors relative to the pelvic floor landmarks was identified from the US data. To study the face validity of the pressure recordings, Pearson's correlation coefficient was calculated between the US displacement data and the pressure recorded from the adjacent sensors (each normalized to peak within the trial) for the submaximal pelvic floor muscle contraction. Pressure data (recorded at 500 Hz) were down-sampled to 25 Hz using spline interpolation, and low-pass filtered at 0.5 Hz (second-order Butterworth filter).
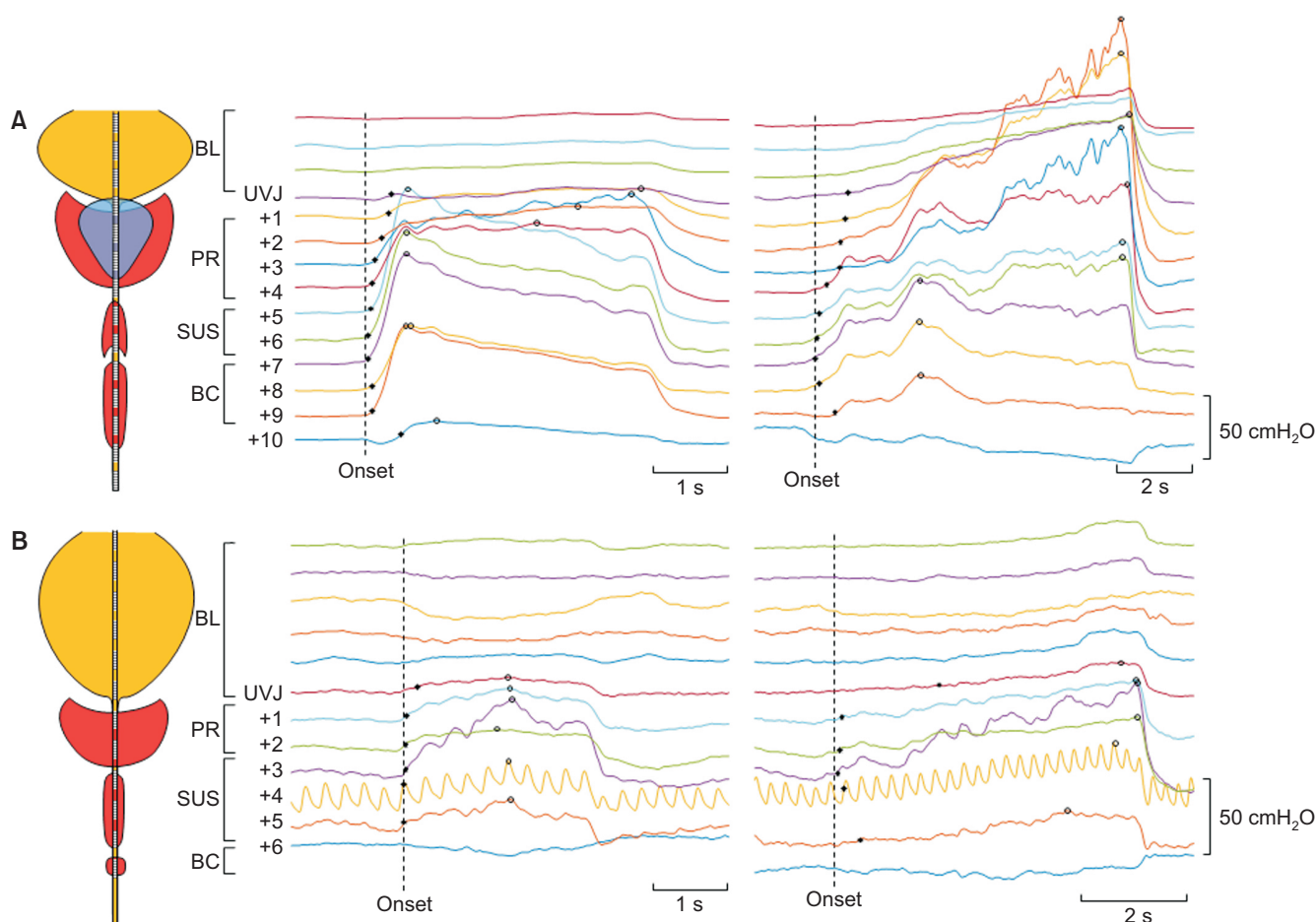
Fig. 3. Simultaneous recording of urethral pressure at multiple sites along the urethra in the male (A) and female (B) during a sub-maximal voluntary contraction (left panel) and a ramped pelvic floor muscle contraction to maximum (right panel). *, the time of onset of increase in pressure at each sensor; °, the time of peak pressure. BL, bladder; PR, puborectalis; SUS, striated urethral sphincter; BC, bulbocavernosus; UVJ, urethrovesical junction.

RESULTS

1. Feasibility

Increases in pressure were successfully recorded from all sensors located adjacent to pelvic floor muscles in all tasks in both participants. This supports the viability of the device for recording urethral pressure (Aim 1). Catheter location was confirmed by identification of which sensors were located in the bladder by the absence of a pressure increase during voluntary pelvic floor muscle contraction (Fig. 3). Pressure increases in the urethra during contraction were observed over a 9 cm region in the male and a 5 cm region in the female. Throughout the experiment for the female participant, a pressure pattern representative of a spasmodic involuntary contraction was observed in the region of the female SUS as reported previously (Fig. 3B) [7,19,20].

2. Face validity: Comparison with transperineal US imaging

During sustained contraction, displacements measured from US were correlated with pressure data. This provides face validity that changes in urethral pressure reflect activation of different muscles. During sub-maximal contraction for the male participant, the correlation coefficients were 0.96, 0.87, and 0.78 for pressure and displacement related to SUS, PR and BC, respectively. For the female participant, the correlation coefficients were 0.85 and 0.92 for activation of BC and PR, respectively.

3. Initial physiological findings using the new technique

When the male participant contracted the pelvic floor muscles sub-maximally, the onset of increase in urethral pressure occurred adjacent to the BC muscle, followed by a pressure increase more proximally, indicating distal-proximal urethral pressure increase (Fig. 3A). Peak pressure was 91
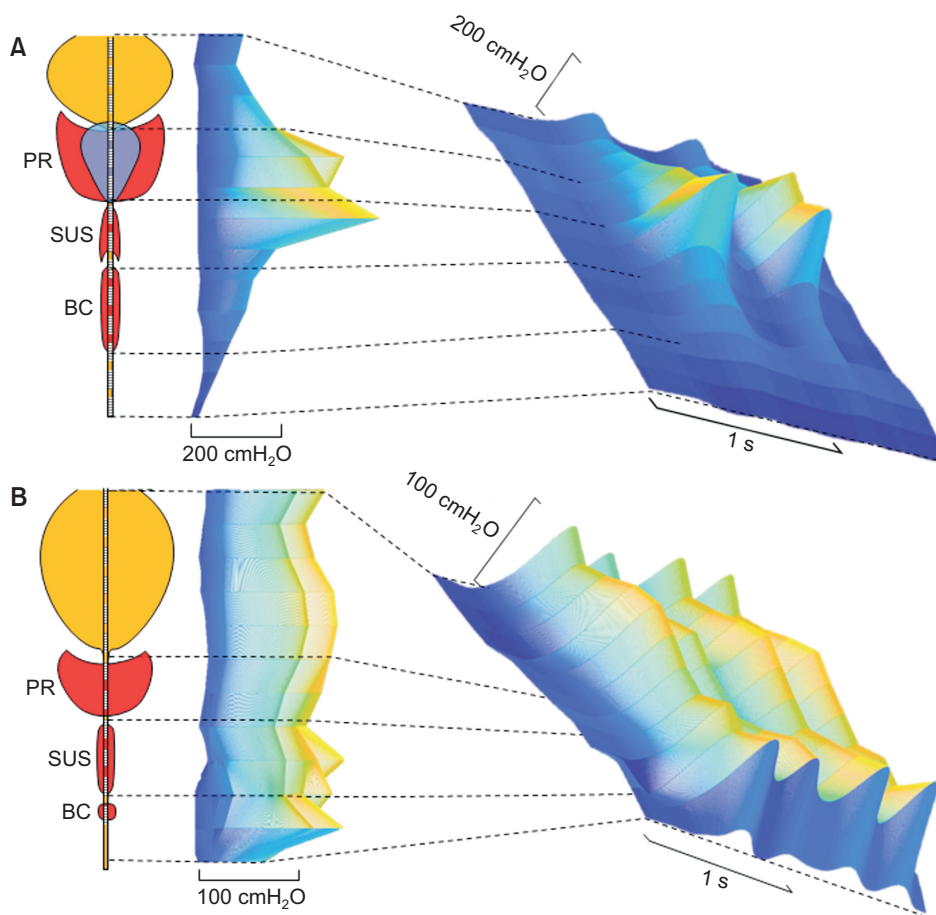
Fig. 4. Two-dimensional and three-dimensional plots of the urethral pressure profile in the male (A) and female (B) during an evoked cough. The two-dimensional plot highlights the location of peak pressures and the three-dimensional plot enables visualization of spatial distribution of urethral pressure over time. PR, puborectalis; SUS, striated urethral sphincter; BC, bulbocavernosus.

cmH_2O which occurred at the location of the SUS. Time and amplitude of peak pressure differed across locations along the urethra; peak pressure adjacent to the SUS was achieved 392 ms after onset of submaximal contraction, but not until 3 seconds for PR (Fig. 3A).

Ramped maximal voluntary contraction (MVC) performed by the male participant induced peak urethral pressure of 190 cmH_2O at the proximal urethra adjacent to the PR muscle (Fig. 3B). Pressure increased by 69 cmH_2O adjacent to the SUS, which was less than that during the submaximal effort. Evoked coughing generated the greatest urethral pressure for the male at PR (239 cmH_2O) and SUS (120 cmH_2O), but not BC (71 cm H_2O) (Fig. 4A). Sustained MVC data show a large initial increase in pressure at the distal urethra representative of SUS and BC, and was reduced to approximately 40% of the peak pressure by 3 seconds (Fig. 5A). In contrast, the pressure adjacent to PR was more sustained and increased rather than decreased over time. The amplitudes and times of peak pressure and the slope of the increase for each task at each anatomical landmark are shown in Table 3.

The times of onset and peak urethral pressure increase in the female were similar across sensor locations during the sub-maximal contraction (Fig. 3B). The largest pressure increase was 41 cmH_2O adjacent to the SUS muscle. Evoked coughing in the female produced the greatest pressure increase across tasks but differed to the male in that the urethral pressures were more evenly distributed along the urethra (Fig. 4B). During sustained MVC, the peak urethral pressure adjacent to SUS, and was greater than that recorded at the same location during sub-maximal efforts (Fig. 5B).

DISCUSSION

This proof-of-concept study confirms the viability of use of a multi-sensor fibre-optic pressure catheter to provide high spatial resolution recordings of urethral pressure/constriction. The data provide preliminary evidence of differing patterns of urethral pressure/constriction between tasks and sexes, with the latter explained by differences in anatomy and urethral length. High correlation between pressures and US-measured displacement induced by contraction of individual muscles provides face validity of the interpretation of pressure recordings with respect to individual muscles. These data form the foundation for detailed investigations of the male and female continence mechanisms and highlight some
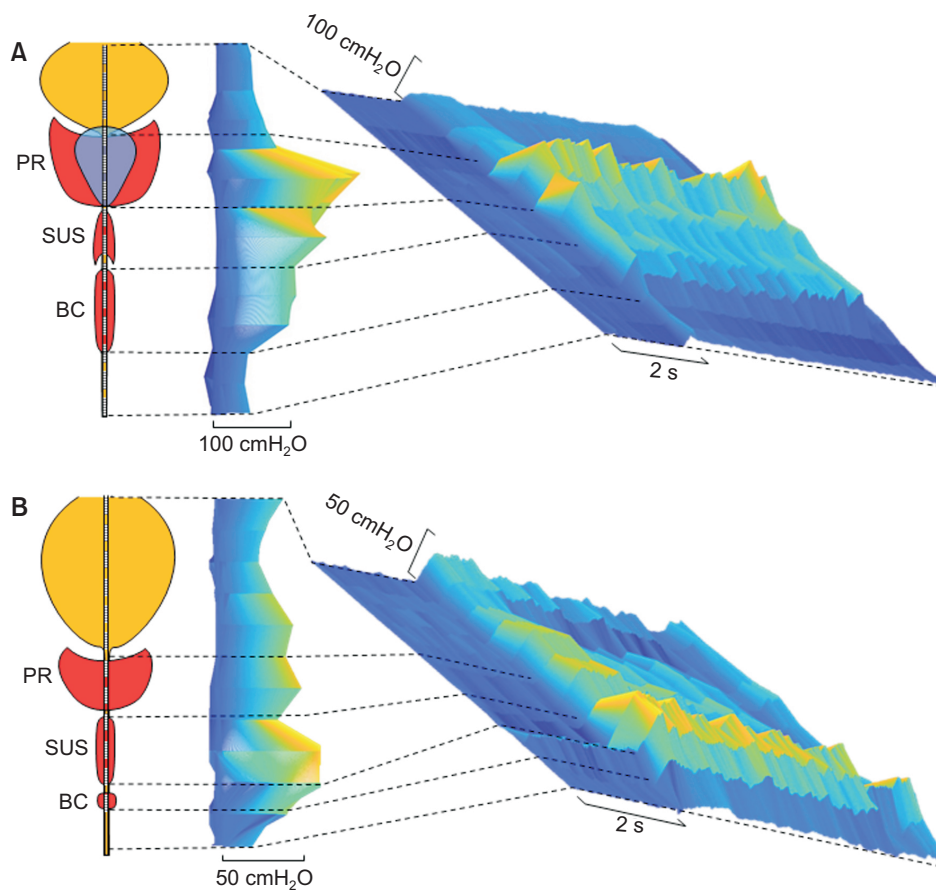
Fig. 5. Two-dimensional and three-dimensional plots of the urethral pressure profile in the male (A) and female (B) during a sustained maximal voluntary contraction. The two-dimensional plot highlights the spatial location of peak pressure and the three-dimensional plot enables visualization of spatial distribution of urethral pressure over time. PR, puborectalis; SUS, striated urethral sphincter; BC, bulbocavernosus.

Table 3. Temporal and spatial data of urethral pressure

		Male			Female		
		PrU	MU	BP	PrU	MU	BC
Submaximal voluntary pelvic floor muscle contraction	Onset time[a] (s)	0.14	0.03	0.00	0.71	0.64	0.13
	Peak time (s)	3.01	0.39	0.42	3.54	3.91	3.05
	Peak pressure (cmH$_2$O)	24	91	87	15	41	18
	Onset slope (cmH$_2$O/s)	8.4	252.8	207.1	5.3	12.5	6.2
Ramped pelvic floor muscle contraction	Onset time (s)	0.73	0.15	0.01	2.09	0.03	0.00
	Peak time (s)	6.35	6.84	4.19	8.79	10.81	12.37
	Pressure (cmH$_2$O)	190	69	63	23	68	37
	Onset slope (cmH$_2$O/s)	33.8	10.3	15.1	3.4	6.3	3.0
Evoked cough	Onset time (s)	0.02	0.02	0.02	0.05	0.04	0.02
	Peak time (s)	0.35	0.32	0.34	0.28	0.29	0.29
	Pressure (cmH$_2$O)	239	120	71	75	84	88
	Onset slope (cmH$_2$O/s)	724.2	400.0	221.9	326.1	336.0	325.9
Sustained maximum voluntary contraction of pelvic floor muscles	Onset time (s)	0.15	0.08	0.03	0.45	0.36	0.00
	Peak time (s)	11.05	0.77	0.79	8.69	8.67	1.72
	Pressure (cmH$_2$O)	168	131	92	49	75	55
	Onset slope (cmH$_2$O/s)	15.4	189.9	121.1	5.9	9.0	32.0

PrU, proximal urethra; MU, mid-urethra; BP, bulb of the penis; BC, bulbocavernosus.
[a]:Times are expressed relative to the earliest time of pressure increase at any location.

potential options for improvement of the catheter design for urethral pressure recordings.

1. Relationship between urethral pressure and US-measured displacements induced by muscle activation

Previous investigations in males [6,11,21] and females [22] have inferred activation of striated pelvic floor muscles from US-measures of displacement of the urethra, which have been validated as indirect measures of muscle activation [11] and assumed to reflect changes in urethral pressure. The correlation between pressure and movement support the face validity of the pressure measures and provide the first data to support this interpretation of US measures. The spatial location of pressure changes and movements support the interpretation of urethral pressure in relation to contraction of discrete striated muscles of the pelvic floor.

2. Methodological considerations

Although data support the feasibility and face validity of the multi-sensor catheter to measure urethral pressure, the findings highlight some possible improvements for the design. First, the catheter lacks a method for stabilization, which creates the possibility for artefacts due to motion (similar to EMG recordings [23]). Future designs could consider addition of a stabilization method to overcome this issue. Second, given the close proximity of the striated pelvic floor muscles to each other, smaller spacing of the sensors to improve spatial resolution would be ideal. Third, visualization of the location of the catheter using US could be enhanced by inclusion of a hyperechoic region on the catheter.

3. Physiological insights

Voluntary contractions performed by the male showed evidence of a distal-to-proximal sequence of urethral pressure increase, which began in the region of the BC muscle. Although this has not been previously observed with pressure data, onset of motion of the distal urethra has been reported during cough [24]. Differences in onset of pressure increases were less pronounced in the female, possibly because of the shorter urethra or because of a potential difference in function of the BC muscle between the sexes. In males, repeated rapid contractions of BC are required for ejaculation, and this function which is unique to males may relate to differences in fatigability and onset time of the muscle. During both sub-maximal contraction and sustained MVC, male pressure data show a large initial increase adjacent to the SUS muscle, followed by a rapid decline. As pressure adjacent to SUS was decreasing, the pressure adjacent to PR either increased or maintained, which implies independent control of these muscles. The rapid decline in distal pressure would suggest rapid fatigue of the male SUS, which concurs with observations of the anal sphincter [8]. The greatest increases in urethral pressure in the female urethra consistently occurred adjacent to the SUS, which concurs with earlier findings of maximum pressure at this location in females [3,25-27].

CONCLUSIONS

The high spatial-resolution pressure catheter successfully recorded urethral pressure in a male and a female participant, confirming the feasibility of the method. Correlation between urethral pressures and motions observed on transperineal US support the face-validity of interpretation of pressure with respect to discrete muscles. Data show preliminary evidence of differences in patterns of urethral pressure increase between sexes.

CONFLICTS OF INTEREST

John Arkwright designed and manufactured the fibre-optic pressure catheter, and is a director and major shareholder in Arkwright Technologies Ltd, a company making fibre-optic sensors. No commercial funding or support was granted for this work. The authors declare no other conflict of interest.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Ryan E. Stafford, Paul W. Hodges, John Arkwright, and Phil G. Dinning. Data acquisition: Ryan E. Stafford, Wolbert van den Hoorn, and Paul W. Hodges. Statistical analysis: Ryan E. Stafford and Wolbert van den Hoorn. Data analysis and interpretation: Ryan E. Stafford, Paul W. Hodges, Wolbert van den Hoorn, John Arkwright, and Phil G. Dinning. Drafting of the manuscript: Ryan E. Stafford and Paul W. Hodges. Critical revision of the manuscript: all authors. Obtaining funding: Paul W. Hodges and Ryan E. Stafford. Administrative, technical,

or material support: Wolbert van den Hoorn and John Arkwright. Approval of the final manuscript: all authors.

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